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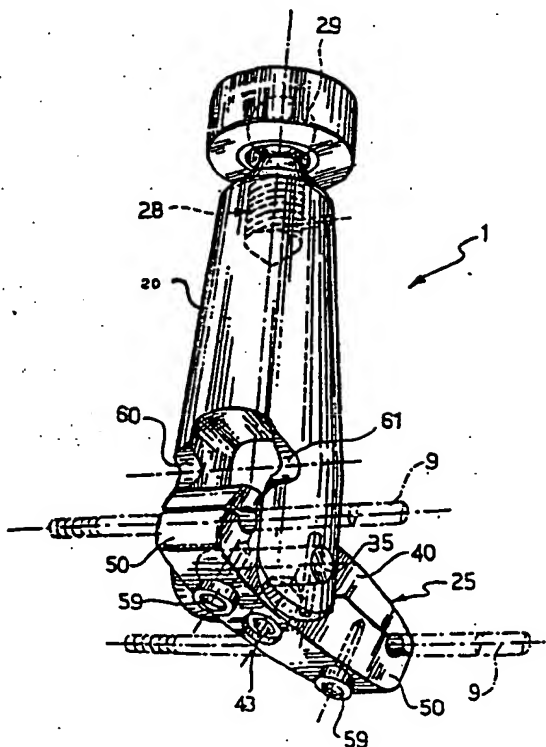
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(57) Abstract

The invention relates to an improved device (1) for external fixation of bone fractures, specifically for ankle fractures, of the type adapted for mounting to a unilateral external fixator and comprising an extendible central body (2) and opposed articulated portions which are connected to respective ends of the central body by ball joints. The device is an ankle clamp having a stem (20), preferably made of a transparent material to X-radiation, with a bifurcate end (21) formed with a pair of prongs (23, 24) having a first jaw portion (40) of a tilting clamp (25) journaled on a pivot (35) provided between the prongs and comprises a second jaw portion (50) coupled to the first jaw portion (40) and fastened thereto by a pair of screws (59).



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"IMPROVED DEVICE FOR THE EXTERNAL FIXATION OF BONES  
FRACTURES, IN PARTICULAR ANKLE FRACTURES"

Field of the Invention

This invention relates to an improved device for the  
5 external fixation of bone fractures, in particular  
ankle fractures.

More specifically, the invention relates to a device  
adapted for mounting to an external fixator and  
comprising an extendible central body and opposed  
10 articulated portions which are connected to respective  
ends of the central body by ball joints.

Prior Art

The use of external fixators capable of setting bone  
fractures in highly delicate regions of the human  
15 skeleton, and especially in the proximity of joints, is  
common practice in the instant field.

As an example, for treating fractures of the tibial  
stem, and to prevent the inception of arthrodesy and  
arthrodiastasis of the ankle, unilateral external  
20 fixators are often used which have a main body and  
articulated portions joined to the central body by  
means of ball joints. The articulated portions are to  
be secured to the tibia and the ankle bones by means of  
rod-like fastening screws.

25 A prior external fixator for setting fractured ankles  
is described, for example, in the International Patent  
Application No. WO97/10775 to this same Applicant.

Also as an example, Figure 1 of the accompanying  
drawings illustrates the use of a fixator sold by the

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Applicant. To more clearly show how this fixator is applied, the perspective view of Figure 1 includes the bone parts affected by the operation, namely a tibia T and tibia-tarsus joint Ts.

- 5 The fixator shown in Figure 1 comprises a central body 2 of substantially cylindrical shape that can be extended axially and has opposite ends attached to respective articulated portions 3 and 4.

10 A first portion 3, referred to as proximal hereinafter, is secured realisably to the tibia by means of rod-like screws 5, which are threaded into the shinbone. Two or three of such screws usually provide sufficient holding power.

15 The proximal portion 3 is connected to one end of the central body 2 through a ball joint 6 which has Allen screw fasteners associated therewith at that end of the central body 2.

20 A second articulated portion 4, referred to as distal portion, is secured realisably to the ankle bones by means of rod-like screws 9 which are threaded into the talus and the calcaneus, respectively. The distal portion 4 is connected to the other end of the central body 2 through a ball joint 6, also having Allen screw fasteners associated therewith.

25 The distal portion 4 is better known in the art as the "ankle clamp", and will be indicated by this term hereinafter.

30 The ankle clamp 4 in Figure 1 comprises a bifurcate stem 10 having a pair of prongs 11, 12 whose free ends mount a clamp member 15. The prongs 11, 12 are bored through across each free end. The through-going bores

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at the two ends are coaxial and accommodate an Allen-head bolt.

The clamp member 15 comprises a pair of jaws 16, 17 having mating inward contours which fit centrally  
5 around the bolt shank and clamp with their ends around the rod-like screws 9 to immobilise the calcaneus and tarsus. Coaxial holes are provided through the opposite ends of the jaws 16, 17 to receive respective bolts 18, 19 for tightening the jaws onto the rod-like screws 9.

10 While being advantageous in many ways and substantially serving its purpose, the above ankle clamp has some drawbacks, as follows.

Since the clamp member 15 with the jaws 16, 17 is fastened to the prongs 11,12 of the bifurcate stem 10  
15 by means of an Allen-head bolt, is difficult for the surgeon to couple the components of the clamp. Moreover, two different clamp members must be used depending to the use on a right or a left limb respectively.

20 Moreover, the clamp stem partly conceals the joint, so that the surgeon is forbidden a clear view of the tibia-tarsus joint, even if radiographic.

This represents a serious shortcoming because a restricted view of the joint makes more difficult  
25 reducing the fracture, and also inspecting the healing bone periodically for later evaluation; most importantly, a restricted view of the joint makes very difficult the locating of the pivot centre of the tibia-tarsus joint, on which depends the proper  
30 positioning of the screws in the calcaneus and the talus for securing the clamp.

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If the pivot centre as estimated by the surgeon does not correspond with the true pivot centre of the ankle, the joint may undergo diastasis and compression, and ligaments become strained.

- 5 To obviate, at least in part, these drawbacks, a solution has been proposed in the art and described in sales catalogues. This prior solution consists of providing the ankle clamp with a C-shaped stem effective to leave the surgical area view unobstructed.
- 10 However, this prior solution is unsatisfactory on account of the following:

The C-shaped stem is not coaxial with the other portions of the fixator, which potentially detracts from the overall structure rigidity;

- 15 A fixator having a C-shaped stem cannot be used for left-side and right-side broken limbs; thus, separate fixators must be made available for application to left and right limbs, since converting an fixator on the occasion of a surgical intervention would be an
- 20 inconvenient and complicated procedure;

The C-shaped stem produces an offset bulk which can be of hindrance to the surgeon during the operation, as well as to the convalescing patient;

- Finally, there still exists a blocked direction to X-
- 25 raying.

The underlying technical problem of this invention is that of providing an improved ankle clamp which can be easily and directly used for both left- and right-side broken limbs.

- 30 Another aim of the present invention is that of

- 5 -

contriving an improved ankle clamp having such construction and functional features to provide the surgeon with an unrestricted view of the joint being treated from all directions, while holding the fixator  
5 coaxial with the ankle clamp mounted to it.

#### Summary of the Invention

The above technical problem is solved by a device as previously indicated and defined in the characterising portions of Claim 1 and following.

- 10 The features and advantages of an ankle clamp according to the invention will be apparent from the following description of an embodiment thereof, given by way of non-limiting example with reference to the accompanying drawings.

#### 15 Brief Description of the Drawings

Figure 1 is a perspective view showing schematically a state-of-art external fixator for reducing broken ankles.

- 20 Figure 2 is a perspective view of an ankle clamp according to this invention.

Figure 2A is a partly exploded view showing the ankle clamp of Figure 2 in perspective.

Figure 2B is a further perspective view of the ankle clamp of Figure 2 in use.

- 25 Figures 3 and 4 are an elevation and a part-sectional view, respectively, of the clamp of Figure 2, as viewed from one side and head-on.

Figures 5 and 6 are an elevation and a part-sectional view, respectively, of a detail of the clamp of Figure

- 6 -

2, as viewed head-on and from one side.

Figure 7 is a view from below of the same detail as in Figure 5.

Figures 8 and 9 are an elevation and a part-sectional view, respectively, of the clamp of Figure 2, as viewed from one side and head-on at different angular settings of its parts.

Figures 10, 11 and 12 are front, vertical cross-section, and bottom views, respectively, of a detail of the clamp of Figure 2.

Figures 13, 14 and 15 are top, front, and bottom views, respectively, of a further detail of the clamp of Figure 2.

Figures 16 and 17 are respective elevation views of the clamp of Figure 2, as viewed head-on and from one side, with only the detail of Figure 10 in place.

Figure 18 is a schematic elevation view illustrating an application of the ankle clamp according to the invention to an external fixator.

## 20 Detailed Description

Referring in particular to the example of Figure 2 of the drawings, generally and schematically shown at 1 is an improved device according to this invention, adapted for external fixation of fractures, specifically a broken tibia stem and broken ankle.

The device 1 is intended for mounting to a unilateral external fixator for reducing fractures, e.g. the fixator previously discussed in relation to Figure 1.

As said before, a fixator adapted to incorporate the

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device 1 would comprise a central body 2 and opposed portions articulated to respective ends of the central body. The device 1 of this invention forms one of these articulated portions, specifically the distal  
5 articulated portion defining an ankle clamp.

This ankle clamp comprises a main body formed as an elongate stem 20 of frusto-conical shape, and a tilting clamp 25 mounted pivotally to one end of the stem 20.

The stem 20 has one end 21 connected to the central  
10 body of the fixator, which end will be termed the upper end hereinafter. The other or lower end of the stem 20 is bifurcated and includes a pair of prongs 23, 24 having the tilting clamp 25 mounted therebetween.

In a known manner, a socket 27 is provided in the upper  
15 end 21 of the stem 20 for receiving a threaded stud 28 formed with a ball head 29. The socket extends coaxially with the axis Y of the stem 20, and is communicated laterally to a hole 30 drilled transverse to the axis Y, as shown in Figure 6. The hole 30  
20 accommodates a lockpin 31 to block the stud 28 in the end 21 of the stem 20.

The ball head 29 of the stud 28 is a part of a ball joint 6 connecting the clamp 1 to the central body of the fixator. The head 29 is received in a mating socket  
25 formed in one end of the central body, and is held in place by an internally grooved ring nut 32.

The lower end of the stem 20 will now be discussed in detail.

The free ends of the prongs 23, 24 are each provided  
30 with a through-going hole 22 whose axis lies transverse to the axis Y of the stem 20. The holes through the two

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ends are coaxial with each other and receive respective opposed ends of a cross-pivot 35 carrying the tilting clamp 25.

Advantageously in this invention, the stem 20 is made of a transparent material to X-ray.

More particularly, the preferred stem 20 is a fiber-reinforced plastics matrix.

In the embodiment under consideration by way of non-limitative example, a polyetherterketone or Peek matrix with a 30% carbon fibre filler is used. The carbon fibres have the purpose of making the clamp stem adequately rigid.

Of course, other matrices and filler proportions could be used instead.

For example, a carbon fibre fill of less than 30%, i.e. in the 20% to 30% range, could still provide sufficient rigidity, and enhance the transparency to X-radiation.

A fibre fill above 30%, i.e. in the 30% to 50% range, could impart sufficient rigidity without significantly deteriorating the characteristic transparency to X-radiation of the inventive stem. Furthermore, different techniques may be employed in the construction of this stem. As an example, the stem could be machined from bar stock, or injection moulded, or formed by an RTM process.

The other parts of the device 1, which need not be transparent to X-radiation, are preferably formed from an aluminium alloy and surface treated by heavy anodic oxidation.

It should be noted that the reinforcing filler confers

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so much strength on the stem 20 structure that additional holes can be drilled therethrough. In particular, the free end of each of the prongs 23, 24 can be drilled with a hole 36 along a parallel  
5 direction to the axis Y of the stem 20.

Each hole 36 crosses the bore 12 accommodating an end of the pivot 35. Each of the holes 36 is to receive a corresponding lockpin 37 for the respective end of the pivot 35.

10 Advantageously, the tilting clamp 25 includes a first jaw portion 40 journalled on the pivot 35 between the prongs 23 and 24 of the stem 20. This jaw 40 comprises a central portion having a rounded outline and wherethrough a central hole 38 is provided. Two opposed  
15 jutting portions 41, 42 are integral with said central portion.

Figure 16 is a front view of an example of the ankle clamp according to the invention, wherein the lower end of the stem 20 mounts the first jaw 40 only.

20 Provided at each of the jutting portions 41, 42 ends are respective semicylindrical sockets 44, 45 for accommodating a section each of the rod-like screws fitted in the talus or the calcaneous, in co-operation with a mating socket formed in a second jaw portion 50  
25 of the tilting clamp 25 and described hereinafter.

The axes of the two semicylindrical sockets 44, 45 lie parallel to and in the same plane P as the axis of the hole 38. Formed in the proximity of each of the ends of the jutting portions 41, 42 is a threaded socket 46, 47  
30 extending through the jutting portions along a perpendicular direction to said plane P.

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Another threaded socket 39 is formed perpendicularly to the axis of the hole 38 in communication with the latter, as shown best in Figure 11.

The threaded socket 39 is to receive an Allen-head screw fastener, e.g. a grub screw, for setting the portion 40 of the tilting clamp 25 to a preferred position, as decided by the surgeon, where said plane P would be inclined at a predetermined angle to the axis Y of the stem 20.

10 The tilting clamp 25 comprises a second jaw 50 whose internal contour matches that of the first jaw 40. This second jaw 50 also has jutting portions 51, 52, each provided with a respective semicylindrical socket 54, 55 in its end for cooperation with the matching sockets 15 44, 45 in holding a section of one of the rod-like screws 9 fitted in the talus or the calcaneus.

The jaws 40 and 50 are brought together with their internal contours in mating relationship, and secured by a pair of screw fasteners 59 passed through holes 20 56, 57 drilled in the second jaw 50 in alignment with the threaded sockets 46, 47 of the first jaw 40. Preferably, the screws 59 are Allen screws.

Furthermore, a hole 58 through the second jaw 50 allows the screw 43 to reach as far as the threaded socket 39 and engage it. In this way, the pivotal movement of the 25 tilting clamp 25 can be stopped by tightening down the screw 43 in its threaded socket 39 such that it will interfere with the pivot 35 and produce a binding action.

30 Referencing to the axis Y of the stem 20, and assuming for the tilting clamp 25 an inclination angle of 0° with respect to the plane P lying perpendicularly to

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the axis Y, as shown in Figure 4, an angular travel through a range of at least  $+44^{\circ}$  to  $-58^{\circ}$  is ensured for the portion 40.

5 This wide angular travel range, wider than any other prior solution, is also contributed by another feature of the ankle clamp according to this invention.

10 Lateral recesses 60 and 61 are provided, in fact, in the stem 20, on one side thereof, and in each of the prongs 23, 24 close to their attaching bases to the stem 20.

15 These recesses 60, 61 allow the angular travel range of the tilting clamp 25 to be extended, since one of the rod-like screws 9 used for securing to the talus or the calcaneus, being held in the jaws 40, 50 and extending transverse to the axis Y of the stem 20, can be accommodated within the recesses 60, 61 and made to abut against the prongs 23, 24.

20 Thus, the device of this invention does solve the technical problem, and achieves a number of advantages, foremost among which is that the X-ray transparency of the clamp stem affords the surgeon an unrestricted view of the joint affected by the fracture reduction operation from all perpendicular directions to the tibia axis.

25 In addition, the tilting portion of the clamp can be used in an universal and reversible fashion on a right-side limb or a left-side limb, this being accomplished without the clamp structure or the application technique having to be altered.

30 As can be appreciated, the tilting portion of the clamp may even be used on stem that don't present the feature

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of the X-ray transparency.

The clamp of this invention can be made of materials which allow of full preparatory sterilisation. In fact, this clamp can be sterilised by any of the most widely  
5 used processes, such as steam, ethylene oxide, or gamma radiation sterilisation.

The ankle clamp of this invention has an important advantage in that it can be retrofitted to existing  
10 fixators, thereby furnishing them with X-ray transparency in the area of the tibia-tarsus joint, as well as with universal applicability to either side limbs.

Changes and modifications can be made unto the device according to the invention within the scope of the  
15 following claims.

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## CLAIMS

1. An improved device (1) for external fixation of bone fractures, specifically for ankle fractures, of the type adapted for mounting to a unilateral external  
5 fixator and comprising an extendible central body (2) and opposed articulated portions which are connected to respective ends of the central body by ball joints, which device is an ankle clamp having a stem with a bifurcate end (21) formed with a pair of prongs  
10 (23,24), wherein a first jaw portion (40) of a tilting clamp (25) is journaled between said prongs.
2. A device according to claim 1, wherein at each of the free ends of the prongs (23,24) is a through-going bore (12) having a transverse axis to the axis (Y) of  
15 the stem (20), the bores through the prong ends being coaxial with each other and receiving respective opposed ends of a transverse pivot (35) carrying said first jaw portion (40) of the tilting clamp (25).
3. A device according to claim 1, which comprises a  
20 second jaw portion (50) coupled to the first jaw portion (40) and fastened thereto by a pair of screws (59).
4. A device according to claim 1, which comprises a second jaw portion (50) coupled to the first jaw  
25 portion (40), and wherein the pivotal movement of the tilting clamp (25) is stopped by a screw (43) being passed through a hole (58) in the second portion and engaging in a threaded socket (39) provided in the first jaw portion (40), said screw interfering with  
30 said pivot (35).
5. A device according to Claim 2, wherein said first

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jaw (40) comprises a central portion and two opposed jutting portions (41,42) formed integrally with the central portion, said central portion having a bore (38) formed centrally therethrough to accommodate said pivot (35), and comprises a threaded socket (39) formed perpendicularly to the axis of the through-going bore (38) and communicated thereto.

6. A device according to Claim 3, wherein said second jaw portion (50) and said first jaw portion (40) have mating internal contours.

7. A device according to Claim 1, wherein the stem (20) has recesses (60,61) formed laterally in each of the prongs (23,24).

8. A device according to Claim 7, wherein said recesses (60,61) are formed in one side of the prongs (23,24) at locations close to the prong attaching base to the stem (20).

9. A device according to claim 1, wherein said stem (20) is made of a transparent material to X-radiation.

10. A device according to Claim 9, wherein said stem (20) is formed from a fibre-reinforced plastics matrix.

11. A device according to Claim 10, wherein said matrix is polyetherterketone.

12. A device according to Claim 10, wherein said matrix is reinforced by approximately 30% carbon fibre.

13. A device according to any one of claims 2 to 8, wherein said stem is formed from a fibre-reinforced plastics matrix transparent to X radiation.

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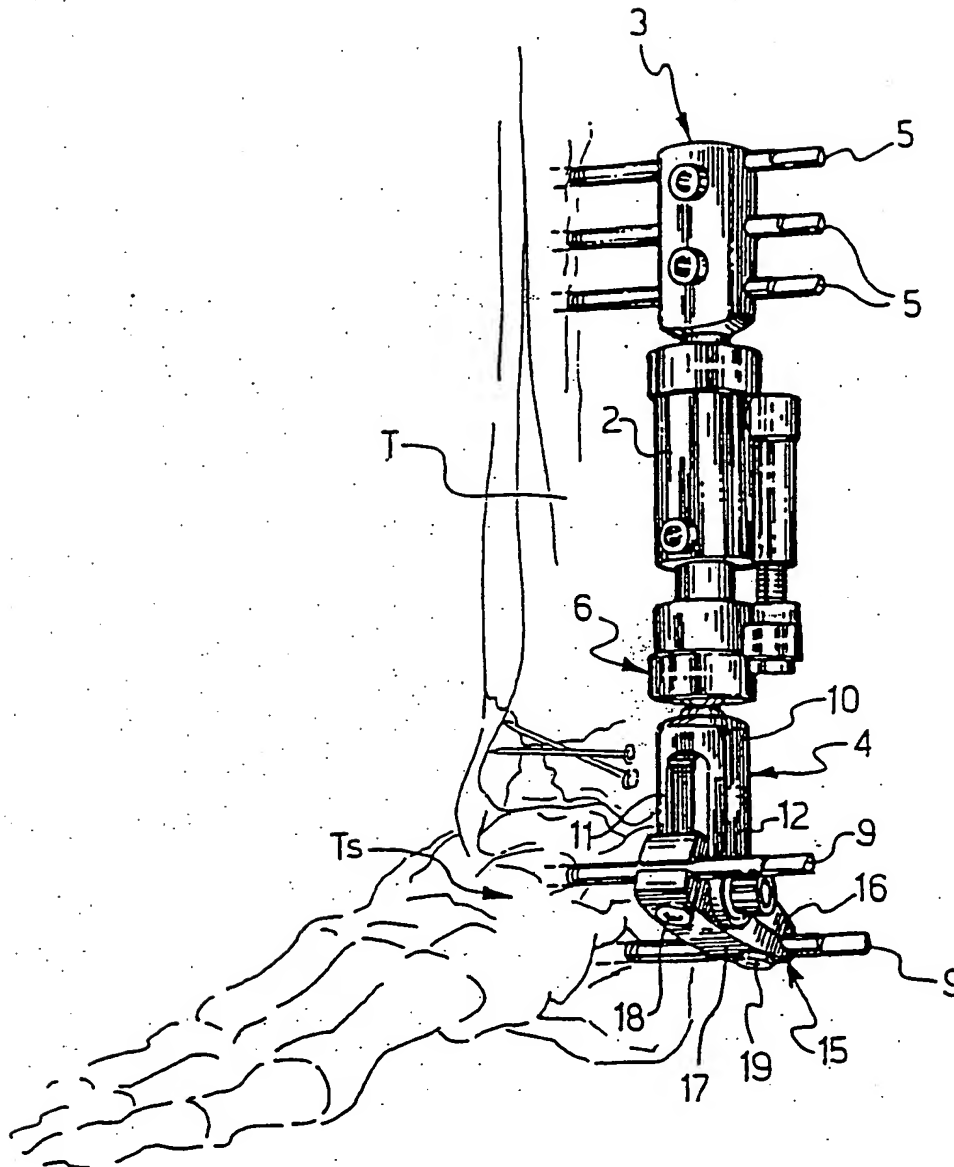


FIG.1

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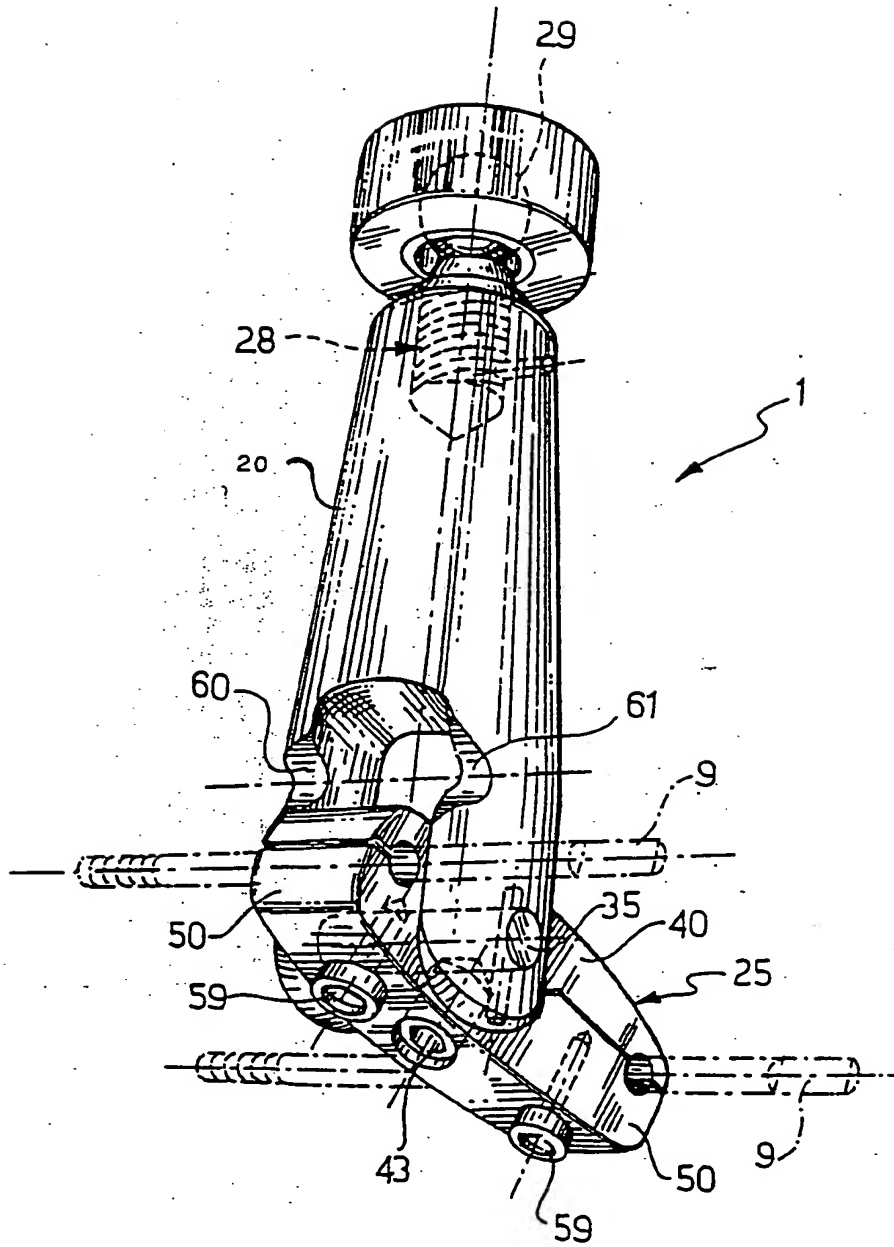


FIG.2

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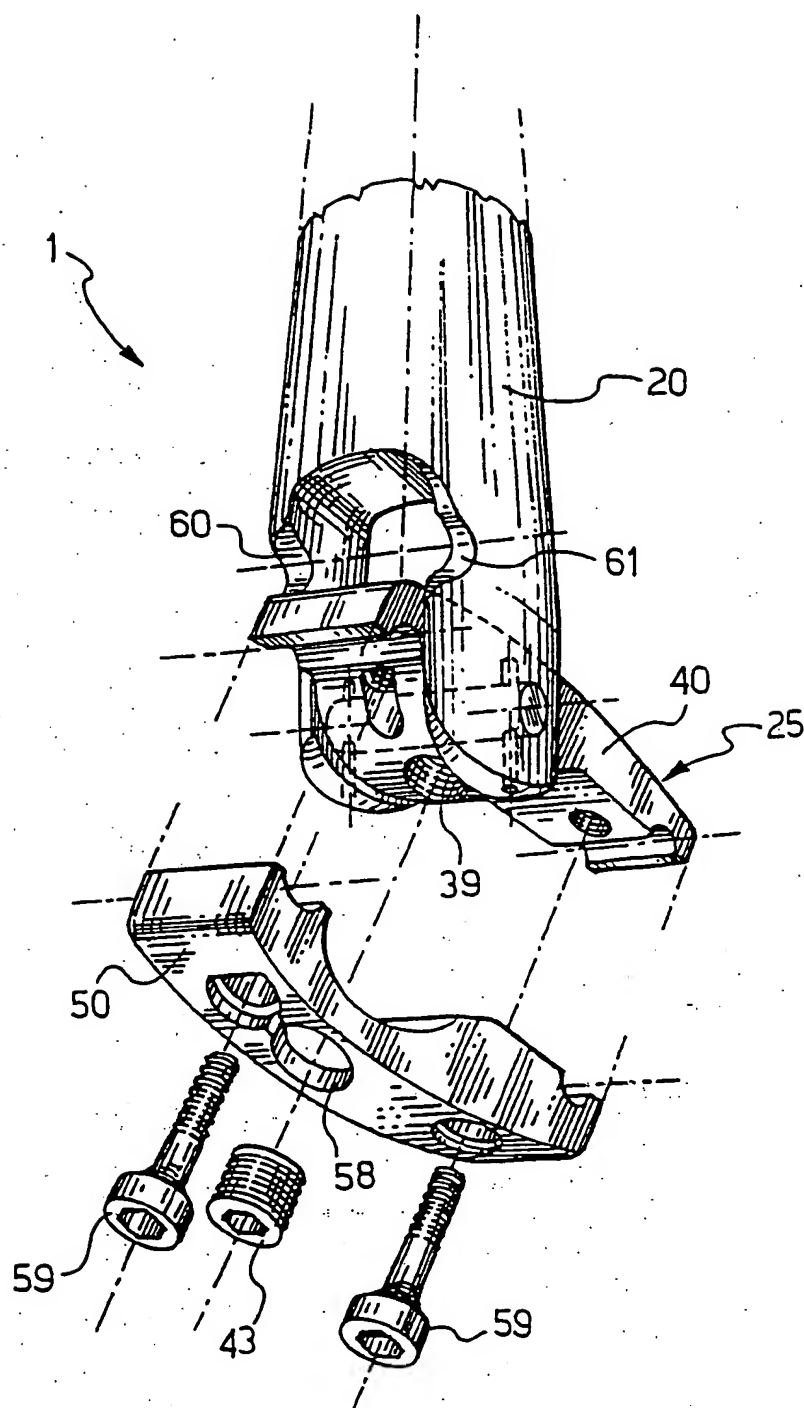


FIG. 2A

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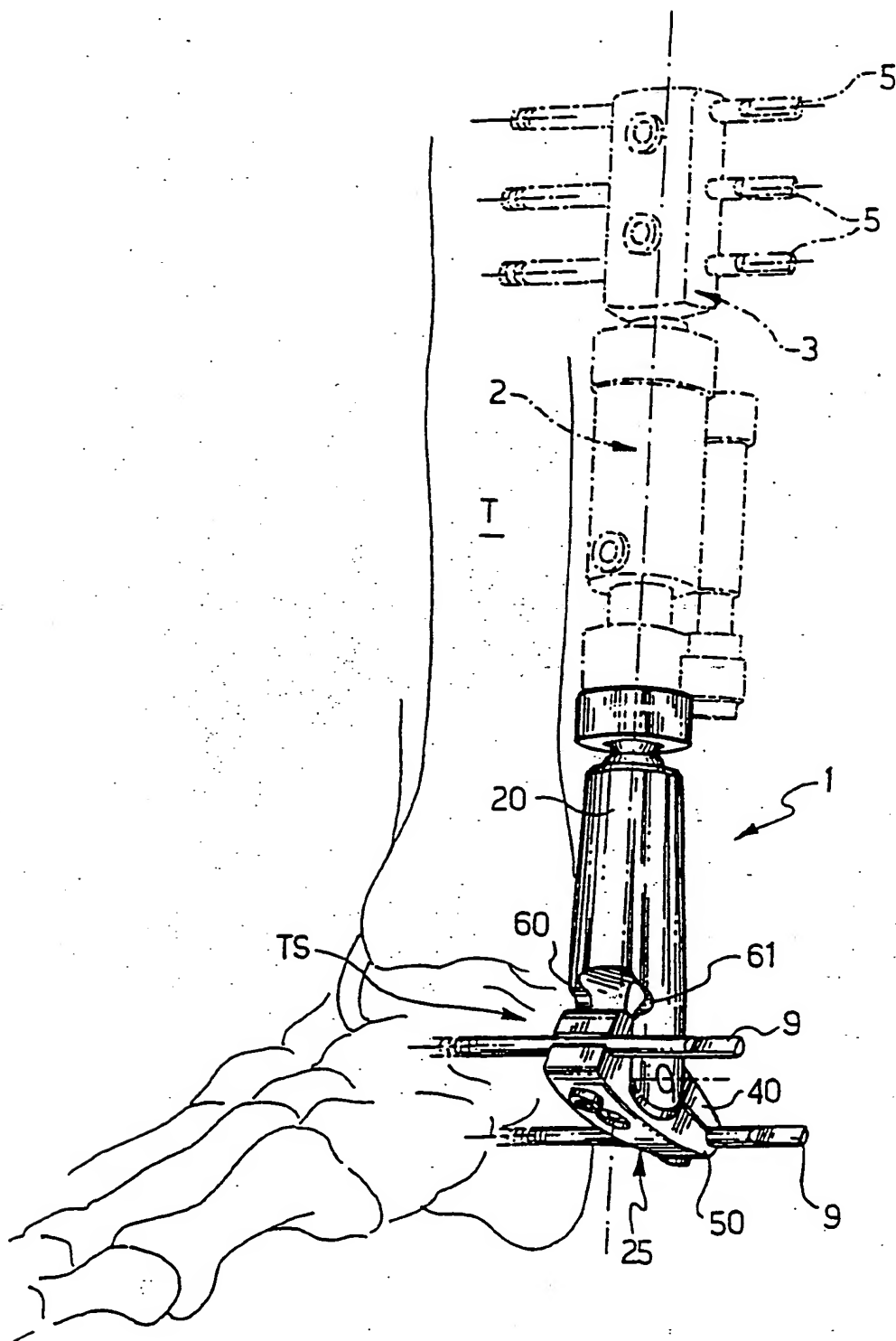


FIG. 2B

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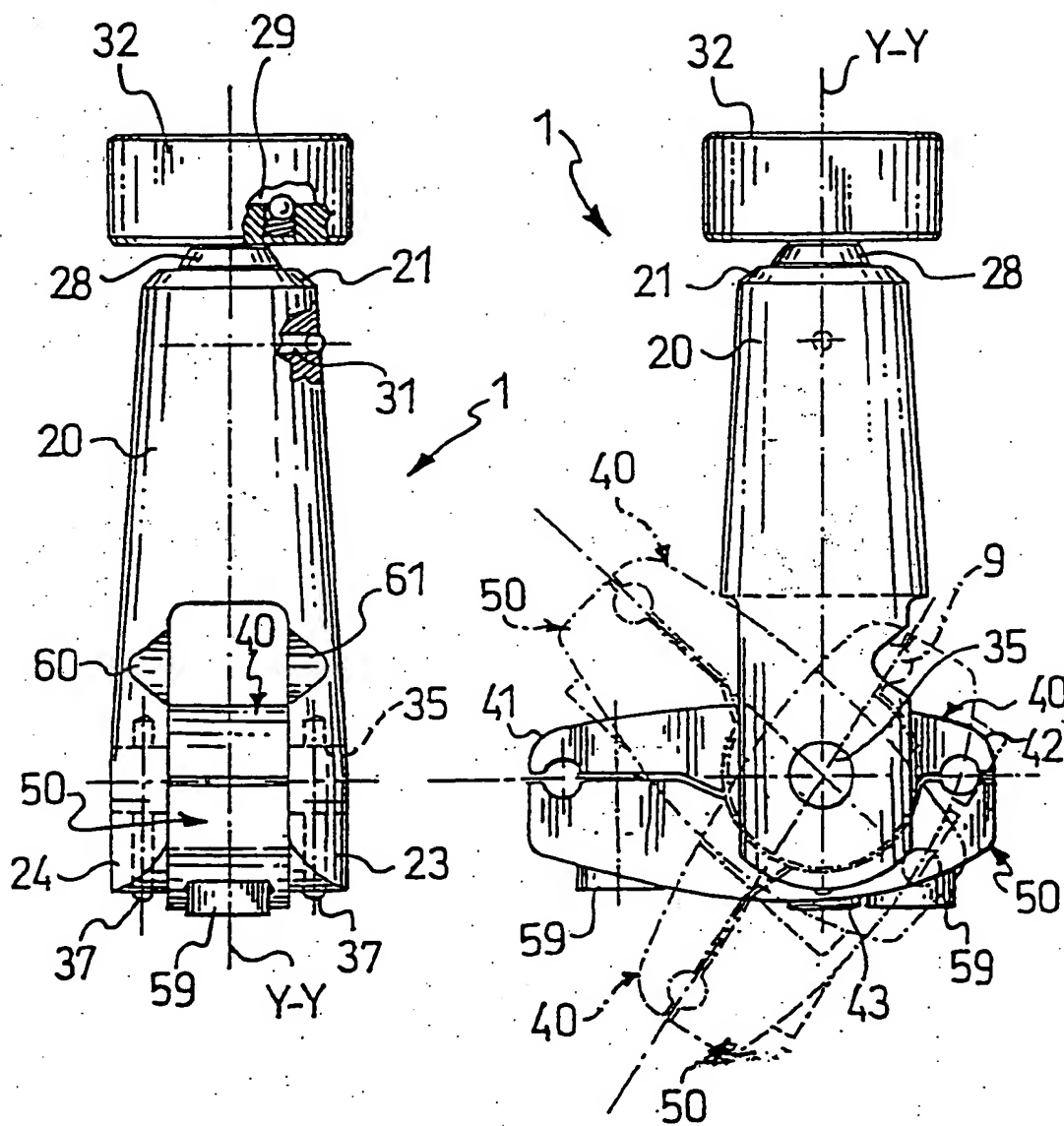


FIG.3

FIG.4

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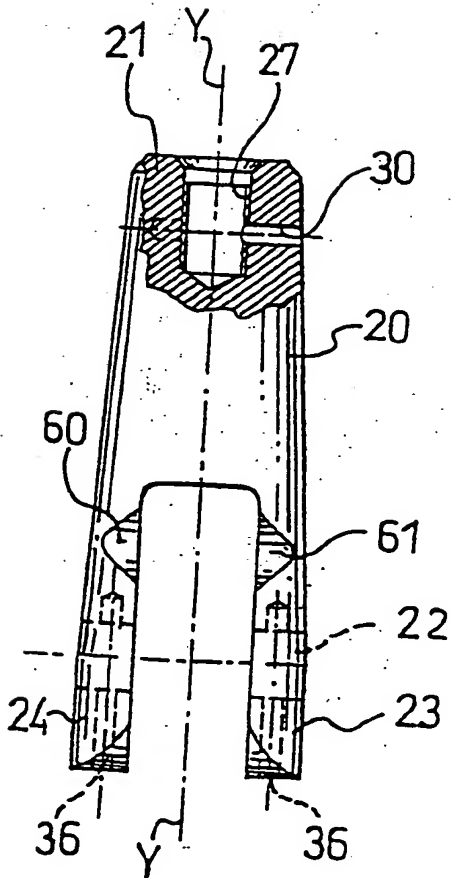


FIG. 6

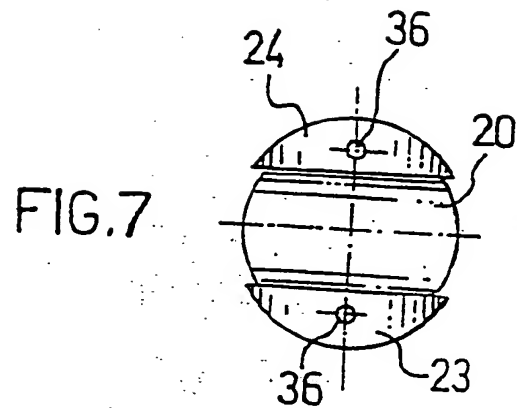


FIG. 7

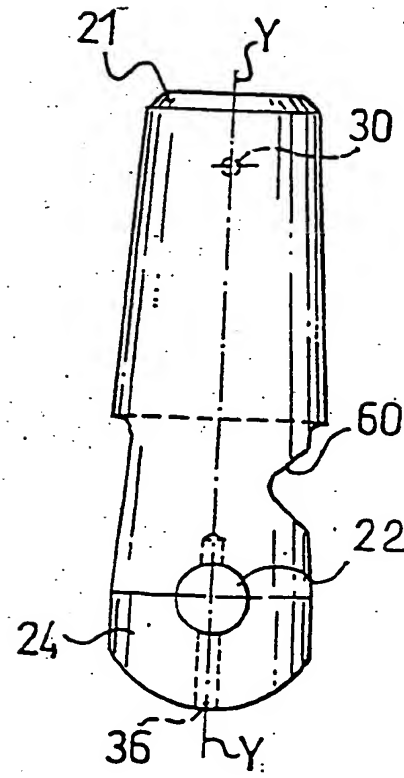


FIG. 5

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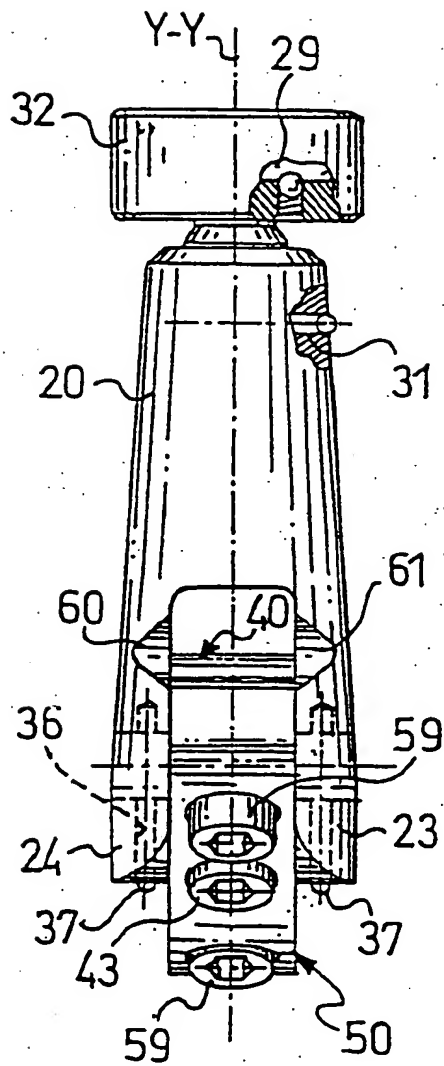


FIG. 8

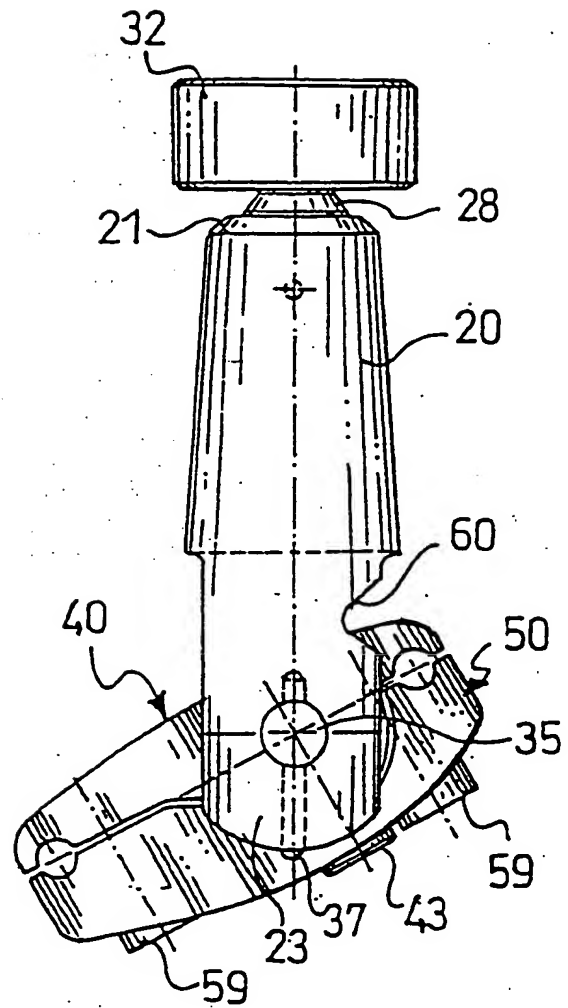


FIG. 9

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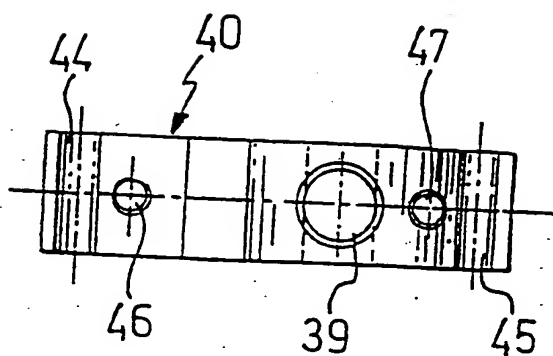


FIG. 12

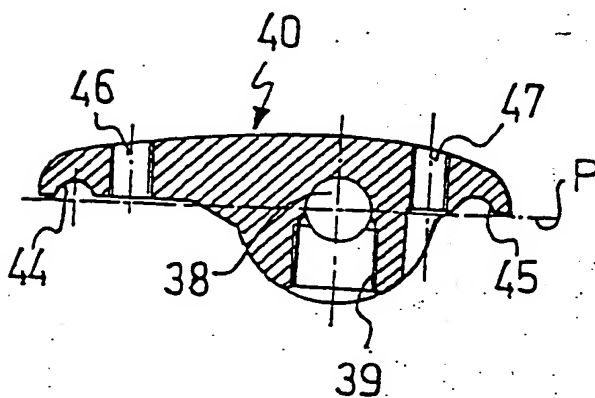


FIG. 11

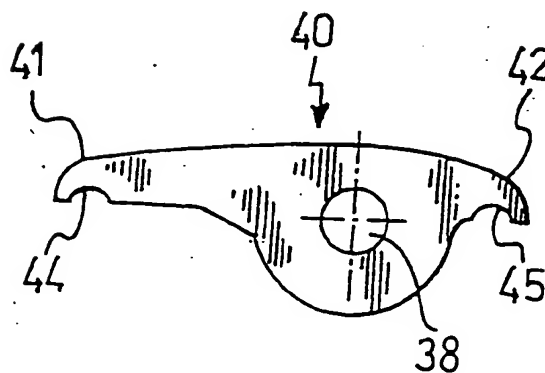


FIG. 10

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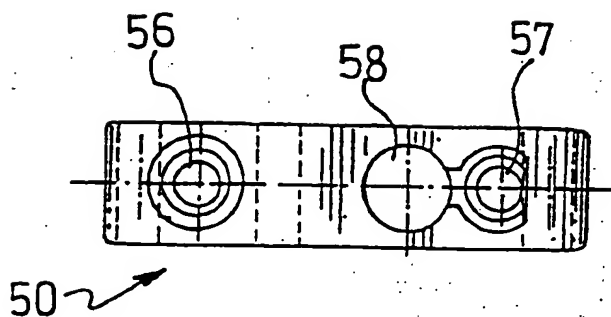


FIG. 15

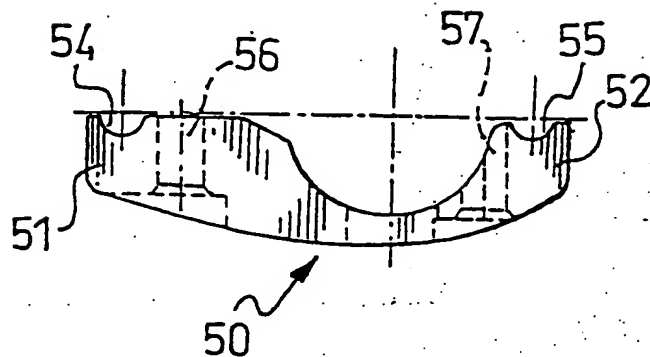


FIG. 14

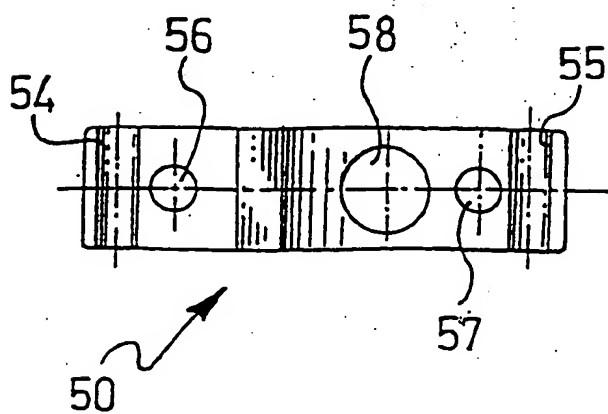


FIG. 13

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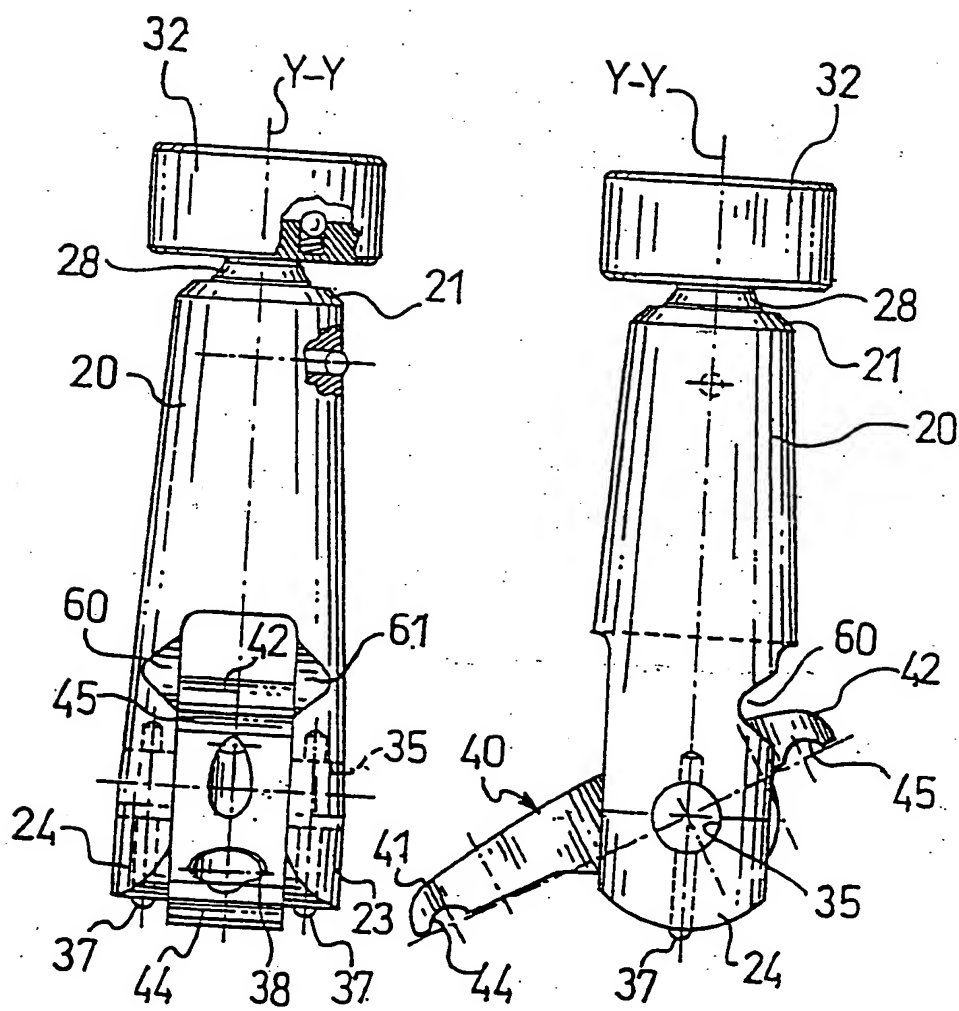
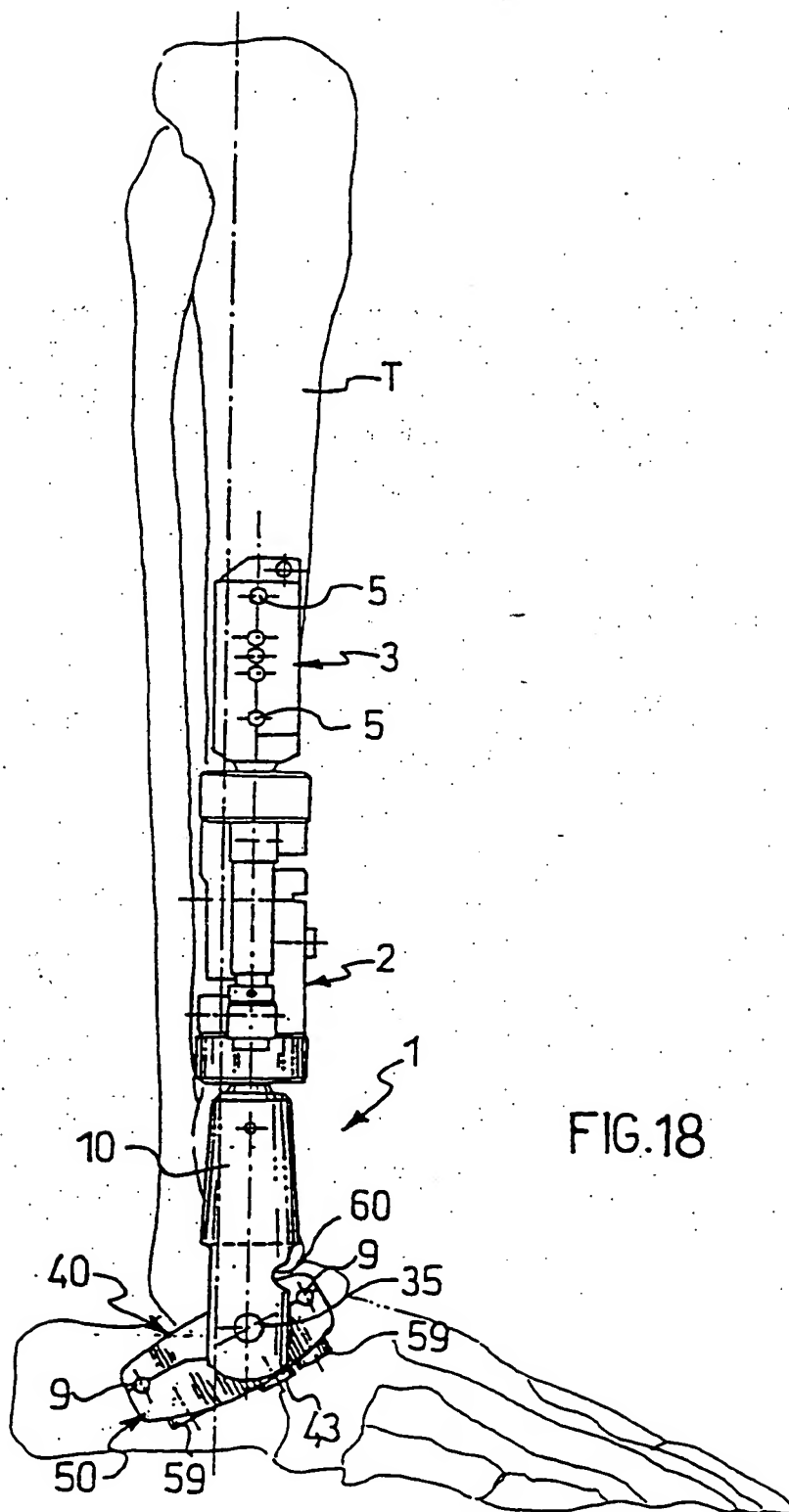


FIG.17

FIG.16

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# INTERNATIONAL SEARCH REPORT

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 7 A61B17/64		International Application No <b>PCT/EP 99/09846</b>
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 10775 A (ORTHOFIX SRL ;FACCIOLI GIOVANNI (IT); MARSH JOHN LAWRENCE (US); VE) 27 March 1997 (1997-03-27) cited in the application claims 1,6; figures 1,3	1-13
A	WO 96 12443 A (PENNIG DIETMAR) 2 May 1996 (1996-05-02) page 10, line 2 - line 31; figure 10	1-13
A	US 5 662 650 A (MAHAFFEY JOHN SCOTT ET AL) 2 September 1997 (1997-09-02) column 7, line 65 -column 10, line 32; figures 15-17	1-13
A	US 2 393 831 A (STADER O) 29 January 1946 (1946-01-29) claim 1; figure 1	1-13
-/-		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <span style="float: right;"><input checked="" type="checkbox"/> Patent family members are listed in annex.</span>		
* Special categories of cited documents : <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p> </div> </div>		
Date of the actual completion of the international search  <div style="text-align: center; font-size: 1.2em;">9 May 2000</div>		Date of mailing of the international search report  <div style="text-align: center; font-size: 1.2em;">18/05/2000</div>
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3018		Authorized officer  <div style="text-align: center; font-size: 1.2em;">Hansen, S</div>

## INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/EP 99/09846

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 27 45 504 A (STRICKLE ERICH) 19 April 1979 (1979-04-19) page 4, line 3 - line 26; figures 1,7	1,9-13
A	EP 0 611 007 A (SQUIBB BRISTOL MYERS CO ;LEE HARRY E (US); RUSSELL THOMAS (US)) 17 August 1994 (1994-08-17) abstract; figures 1-3	1

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Information on patent family members

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